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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,214	04/21/2006	Per Ove Ohman	3042860 US01	2907

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EXAMINER	
SASAKI, SHOGO	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,214	OHMAN ET AL.	
	Examiner	Art Unit	
	Shogo Sasaki	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *3,5 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-14 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendments to the claims are acknowledged.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/2009 has been entered.

Claim Interpretations

3. Regarding claim 2, the limitation "each flow path is connected to a sink of said two or more sinks" was interpreted to mean that the multiple flow paths are each connected to corresponding sinks (for the prior art rejections); instead of the multiple flow paths being connected to one of the multiple sinks and other sinks have no connections to any flow path.

4. Claim 9 does not positively set forth "sub-sections" as part of the claimed subject matter. Said claim does not provide any specific structure that defines said sub-divisions. Thus claim 9 does not further structurally limit previous claims.

5. Regarding the recitation "an external influence selected from the group consisting of heating, cooling, irradiation with visible light, infrared irradiation, vibration, and application of an electric current" in claim 19, the external influences are not structures. Therefore said recitation does not further structurally limit said claim.

6. Regarding claims 1, 2, 4, 6-10, 14, and 21-22 recitations [claim 1] "to achieve a capillary flow" and "creating capillary flow without enclosing said device;" [claim 2] "said device adapted to perform multiple analyses on one liquid sample;" [claims 4, 6-10and 22] entire recitations; [claim 14] "to prevent back flow of said liquid sample;" [claim 21] "configured to induce lateral capillary flow of an introduced liquid sample along at least

one flow path," "for reacting with said liquid sample (A material does not inherently have to be a chemical reagent, therefore the reaction can include physical interactions.)," "for producing an initial lateral capillary flow of said liquid sample" and "wherein said device produces capillary flow without requiring said at least one flow path to be enclosed," which are directed to the manner in which a claimed apparatus is intended to be used do not distinguish the claimed apparatus from the prior art.

7. As to claim 21, it is noted that the claim does not say where the means for controlling is located in the device claimed. (Also see 112(2) rejection.)

8. Claim 21 does not positively set forth "a support surface" as part of the claimed subject matter. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element. "A substrate" does not inherently posses a support surface.

9. As to claims 1 and 23, the recitations [claim 1] "means are applied to…" and [claim 21] "controlling means are applied distally in relation to said reaction or incubation zone" are more so worded to be directed to a process of fabrication rather than defining a structure. The process by which the elements were formed is not further structurally limiting.

Claim Objections

10. A portion of claim 20, specifically "said projections have a height and spacing," is objected to because the new claim 1 already recites said limitations.

11. Regarding claim 21, it is noted that "one" is missing between "at least" and "capillary zone" in line 2.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 2, 4, 6-14 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new limitations "creating capillary flow without enclosing said device" in claim 1, and "wherein said device produces capillary flow without requiring said at least one flow path to be enclosed" in claim 21 were not part of the original disclosure. The subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art. The original specification or the original claims do not mention any casings; or a state of the device claimed being enclosed or not enclosed.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1, 2, 4, 6-14 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed towards a liquid handling device. It is unclear how, for e.g., an element, "a sink," which defines the invention can also be defined as being disposed in a distal end of the device (invention itself). That is similar to a claim claiming a chair comprising a leg disposed at the chair. Said recitation renders claim 1 indefinite. Appropriate correction is required.

Claims 1 and 21 recites "means for controlling the flow rate…" According to the specification, said means is the projections which are already recited and defined in said claims. Both claims are indefinite, because it is unclear what applicant intends said means to be. Further, it is unclear if applicant intends to invoke 112, sixth paragraph. It is noted that a claim limitation will be presumed by the examiner to invoke 112, sixth paragraph. However the phrase "means for" must not be modified by sufficient structure, material, or acts for achieving the specified function.

16. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: The relations between the substrate having zones and the means.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1, 2, 4, 6-14 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Regnier et al. (US 6156273).

Regarding claims 1, 2, 4, 6-14 and 19-23, Regnier et al. disclose a device for handling a liquid sample comprising (column 3, line 36-column 12, line 51):

- at least one flow path (Fig. 6: 107, 108, 109, 114, 116);
- at least one zone (Fig. 6: 99, 118);
- a transport zone (Fig. 6: 112);
- at least one sink (Fig. 6: 100) comprising an area having projections including heights and spacing (Fig. 1B, 14; or Fig. 2A-2F: These are present on the 100 side as well.) substantially vertical to its surface, said projections configured to achieve a capillary flow (The fluid flow in the direction of the arrow 110. Therefore the side 102 must be the source and the side 100 will have to be the sink. The flow paths with or defined by projections of Regnier et al. are capable of causing a capillary flow.);
- wherein said at least one flow path is two or more flow paths (Fig. 6: 107, 108, 109, 114, 116); said at least one sink is two or more sinks (The side 100 in Fig. 6 include channels 104, which is equivalent to 12 on the side 102 (Fig. 1A; column

5, line 61; and column 11, line 31). Any configuration/interconnections of the channel 104 may effectively form variety of sinks.); each flow path is connected to a sink of said two or more sinks (The flow path 109 are connected to corresponding portions of sink having square cross-sectional projections.);

- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 6: 107, 108, 109, 114, 116);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 1 A and 6: The flow path 107-108-109 provides 3 different types of polygonal vertical projections.);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (Fig. 1 A and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections.);
- a design feature (Fig. 1 A; 2A-F and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections; and the sinks provides tetragonal vertical projections or polygonal vertical projections.);
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (Fig. 1 A; 2A-F and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections; and the sinks provides tetragonal vertical projections or polygonal vertical projections.); and
- wherein said projections have heights (Fig. 1A).

19. Claims 1, 2, 4, 6-14 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhullar et al. (US 6451264).

Regarding claims 1, 2, 4, 6-14 and 19-23, Bhullar et al. disclose a device for handling a liquid sample comprising (abstract):

- at least one flow path (Fig. 1: 16, 18, 24, 26, 28);

- at least one zone (Any area in said fluid pathways may be considered a zone.);
- a transport zone (Any portion of said fluid pathways may be considered transport zones.);
- at least one sink (Fig. 1: 20) comprising an area having projections including heights and spacing (Fig. 5, 37, 39; and column 4, lines 57-63) substantially vertical to its surface (These leads are formed via etching/lithography, thus they must protrude from the bottom surface of the site 20.); said projections configured to achieve a capillary flow (The fluid flows to the testing site 20 (column 4, lines 8-13). Therefore the inlet 14 must be the source and the site 20 will have to be the sink. The flow paths with or defined by projections of Bhullar et al. are capable of causing a capillary flow.);
- wherein said at least one flow path is two or more flow paths (Fig. 1: 16, 24, 26, 28); said at least one sink is two or more sinks (Fig. 1: 20); each flow path is connected to a sink of said two or more sinks (Fig. 1);
- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 1: 16, 24, 26, 28; column 4, lines 22-26);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 2 and 3; column 5, lines 1-39);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (Fig. 2 and 3; column 5, lines 1-39);
- a design feature (Fig. 2 and 3; column 5, lines 1-39); and
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (Fig. 2 and 3; column 5, lines 1-39); and
- wherein said projections have heights (Fig. 2).

20. Claims 1, 6-14 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohman et al. (WO 3103835).

Regarding claims 1, 6-14 and 19-23, Ohman et al. et al. disclose a device for handling a liquid sample comprising; and a method of using the same (abstract):

- at least one flow path (Fig. 10);
- at least one zone (Fig. 10, zones 1-3);
- a transport zone (Any zone in said path way may be considered a transport zone, since the fluid flows through them.);
- at least one sink (Fig. 9, The exit with pad 10; and page 11, lines 8-17) comprising an area having projections including heights and spacing (Fig. 9, The exit where 10 is laid on effectively becomes the flow sink as disclosed; and it has vertical projections in that particular area; page 11, lines 1-7) substantially vertical to its surface; said projections configured to achieve a capillary flow (The flow paths with or defined by projections of Ohman et al. are capable of causing a capillary flow.);
- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 11 and 12: 1);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 11 and 12: 1);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (page 5, lines 11-13);
- a design feature (page 5, lines 11-13);
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (page 5, lines 11-13); and
- wherein said projections have heights and spacing (See figures).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohman et al. (WO 3103835).

Regarding claims 2 and 4, Ohman et al. disclose all of the limitations as set forth above.

Ohman et al. do not teach: wherein said at least one flow path is two or more flow paths; said at least one sink is two or more sinks; and each flow path is connected to a sink of said two or more sinks.

However the structure of claim 2 is not different from having two devices of claim 1. (Unless applicant meant the multiple flow paths are connected to one of the multiple sinks and other sinks have no connections to any flow path.)

It would have been obvious to one having ordinary skill in the art at the time of the invention to have two pathways connected to two different sinks. A mere duplication of parts has no patentable significance, since it involves only routine skill in the art.

Regarding claims 2 and 4, recitations directed to the manner in which a claimed apparatus is intended to be used do not distinguish the claimed apparatus from the prior art.

Response to Arguments

25. Applicant's arguments filed 11/23/09 have been fully considered.

26. Applicant's arguments with respect to the prior art rejection have been fully considered but they are not persuasive.

In response to page 7, paragraph 4 to page 8, paragraph 1; and page 9, the microfluidic devices with vertical projections of Bhullar et al. and Regnier et al. are more than capable of causing a capillary flow of a fluid through the flow paths defined by the projections without the cover. It is the surface tension (the surfaces of the projections and the surface of the substrate) that overcomes the intermolecular forces, which pulls/moves the fluid.

In response to page 8, paragraph 2; and page 10 (Below noted argument applies to both claim 1 and 21, such as reaction zone.), for instance a zone cannot be structurally labeled an incubation zone unless some type of heater is also claimed as being adjacent to said zone. Applicant may name/label an element however applicant wishes. However in this case, such an element cannot not be labeled as a particular element that is capable of performing a certain task.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS
12/4/09
/Brian R Gordon/
Primary Examiner, Art Unit 1797